

Message

From: Jones, Samantha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EAC77FE3B20C4667B8C534C90C15A830-JONES, SAMANTHA]
Sent: 4/21/2015 3:17:43 PM
To: Newhouse, Kathleen [Newhouse.Kathleen@epa.gov]
Subject: RE: News Update: Science Advisors Ponder New IRIS Skin Cancer Risk Value In BaP Analysis (InsideEPA)

Fortunately she sent me the quotes ahead of time, they were a bit of a mess and I have to tweak them!!! I feel that I was more eloquent in my responses than is conveyed here but oh well ☺

From: Newhouse, Kathleen
Sent: Tuesday, April 21, 2015 11:15 AM
To: Jones, Samantha
Subject: FW: News Update: Science Advisors Ponder New IRIS Skin Cancer Risk Value In BaP Analysis (InsideEPA)

Glad you got some quotes in here. Might have been a bleaker story without them!

From: Bland, Naseera
Sent: Tuesday, April 21, 2015 4:59 AM
To: Alcalá, Cecilia; Alexander, Laurie; Avery, James; Bateson, Thomas; Berner, Ted; Birchfield, Norman; Bland, Naseera; Blessinger, Todd; Boone-Edwards, Amanda; Brinkerhoff, Chris; Buckley, Barbara; Burgoon, Lyle; Bussard, David; Cai, Christine; Carmichael, Brenda; Choudhury, Harlal; Coglianò, Vincent; Corona, Elizabeth; Cubbison, Christopher; CURTIS, LUCY; D'Amico, Louis; Deener, Kathleen; Euling, Susan; Evans, Amanda; Field, Malcolm; Fite, Katherine; Flowers, Lynn; Frithsen, Jeff; Fritz, Jason; Galizia, Audrey; Gamble, Janet; Gatchett, Annette; Gibbons, Catherine; Glenn, Barbara; Grambsch, Anne; Gwinn, Maureen; Haque, Mefruz; Hawkins, Belinda; Hogan, Karen; Hotchkiss, Andrew; Iuliano, Kayla; Jarabek, Annie; Jinot, Jennifer; Johnson, Maureen; Jones, Samantha; Kadry, Abdel-Razak; Keshava, Nagalakshmi; Kopylev, Leonid; Kraft, Andrew; Lee, Janice; Lin, Yu-Sheng; Long, Tom; Luke, April; Makris, Susan; Murphy, Patricia; Nath, Raghu; Newhouse, Kathleen; Olden, Kenneth; Owens, Beth; Pardo, Larissa; Perovich, Gina; Persad, Amanda; Petersen, Dan; Powers, Christina; Pratt, Margaret; Preuss, Peter; Reid, Jon; Rieth, Susan; Ross, Christine; Ross, Mary; Rutigliano, Marian; Salazar, Matt; Sams, Reeder; Samuels, Crystal; Sanchez, Yolanda; Sasso, Alan; Schappelle, Seema; Schlosser, Paul; Segal, Deborah; Shams, Dahnish; Shaw, Denise; Slimak, Michael; Sonawane, Bob; Spassova, Maria; Suter, Glenn; Taylor, DebraLynn; Troyer, Michael; Vandenberg, John; Vinikoor-Imler, Lisa; Vulimiri, Suryanarayana; Walker, Teneille; Walsh, Debra; Weaver, Andre; White, Paul; Woodall, George; Wright, Michael; Yang, Hui-Min; Zwayer, Bette
Subject: News Update: Science Advisors Ponder New IRIS Skin Cancer Risk Value In BaP Analysis (InsideEPA)

RISK POLICY REPORT - 04/21/2015

Science Advisors Ponder New IRIS Skin Cancer Risk Value In BaP Analysis

Posted: April 20, 2015

Experts reviewing EPA's draft assessment of the human health risks of benzo(a)pyrene (BaP) are struggling to determine how best to advise the agency on the first-time dermal cancer risk toxicity value EPA calculated for the petroleum chemical, even as agency managers are planning to soon move to apply the analysis to a broader effort to assess numerous chemicals in its class. EPA's Integrated Risk Information System (IRIS) BaP assessment for the first time presents a cancer risk estimate for dermal exposure. It is also novel because the agency plans to use the finalized BaP risk numbers in an approach to estimate the human cancer risk of polycyclic aromatic hydrocarbons (PAHs) as a class of chemicals.

EPA advisors who met to peer review the draft assessment April 15-17 in Washington, DC, discussed the new dermal cancer risk estimate, or dermal slope factor (DSF), but appeared to be still struggling to reach final conclusions on the issue as the meeting ended.

The advisors will continue to work on crafting their report to EPA over the next months, including a pair of conference calls in August and September.

Panelists raised concerns with how EPA might apply the BaP risk estimates in the future, particularly at existing contaminated sites, as several public commenters argued that the new DSF would create challenges for their clients. Chris Saranko, a toxicology consultant for the Utility Solid Waste Activities Group (USWAG), told the advisory panel that he discussed EPA's proposed DSF of 0.006 per micrograms per day with some regional risk assessors, who raised concerns about what would happen if the DSF were applied to the regional screening levels (RSLs) used to guide remediation at Superfund sites.

"If you basically apply the same methodology but apply the RSLs, . . . and you can't stray from them . . . when you do that, the RSL for all pathways combined is . . . below what EPA considers background" amounts of BaP in the environment, Saranko said.

This is an issue that USWAG and others have raised with EPA in public comments regarding the DSF in the past. USWAG writes in April 8 comments to EPA's Science Advisory Board Chemical Assessment Advisory Committee (CAAC) that "the DSF drives an RSL for residential land use scenarios that is lower than or near the detection limit for BaP/PAHs. This will frustrate and delay cleanups, creating significant hurdles for regulators and regulated entities alike -- without any scientifically sound justification." *Relevant documents are available on InsideEPA.com. (Doc. ID: 180738)*

Alan Stern, a panel member and toxicologist with the New Jersey Department of Environmental Protection said, "As a state risk assessor here, the fact that a given cancer risk is less than background is no reflection on [EPA], it just means that it defaults to background. It has no bearing on the underlying toxicology."

But Saranko replied, "In practice it's a very difficult assessment issue and a very expensive one. It shouldn't be minimized."

Industry commentators also argued, as they have in the past, that existing literature indicated that certain types of skin cancer are caused by UV radiation, rather than exposure to BaP. They suggested that EPA's IRIS assessment overstates BaP's skin cancer risk. Annette Rohr, a toxicologist with Electric Power Research Institute (EPRI), argued, "Our calculations show that dermal contact [with BaP] would account for 26 percent of all skin cancer on the head, hands, lower legs, and forearms for the entire U.S. population," per EPA's risk assessment.

But one advisor, Kenneth Portier, managing director at the American Cancer Society's Statistics and Evaluation Center, said skin cancer is significantly under reported. "Something like 80 percent of skin cancer is not reported to the [cancer] registry," he said.

"That's an important point," Stern replied. If 80 percent of skin cancers are not reported, industry's calculations are off, he said, adding that instead of 26 to 30 percent of skin cancers linked to BaP, it is something like 5 percent.

The panelists discussed a number of uncertainties in the DSF calculation, including differences between mouse and human skin, since the value was calculated from a study of mice whose skin was painted with mixture of BaP and acetone. Panelists also struggled with how to scale from animal to humans, because while EPA has such guidance for oral dosing, it does not have dermal guidance. EPA adopted this bodyweight three-quarters oral scaling factor for the dermal calculation.

As the large panel of advisors struggled to reach common conclusions on how to advise EPA on the DSF, one panelist suggested that not having consensus from the group wouldn't be a problem. SAB reports rarely include discussions of minority and majority recommendations, since their charge is to strive for consensus wherever possible.

"I'm not suggesting that we need consensus. Keep in mind there is no scientific consensus on inhalation scaling," which is a much older problem, said one advisor, Scott Bartell, an associate professor of public health at the University of California Irvine. "At the end of the day I don't think the lack of complete understanding keeps EPA from going forward. Let's not let the perfect be the enemy of the good." Bartell appeared to be joined in his remarks by the panel's chairman, Elaine Faustman, an environmental and occupational health professor at the University of Washington. "I don't want to come back in two years to see another draft. I want to have some numbers to protect children and adults."

By contrast, public commenters urged the panel to recommend that EPA craft a guidance document for how to calculate future DSFs, before publishing a final DSF in the BaP assessment.

Asked after the meeting about the concern, Samantha Jones, associate director for science in EPA's IRIS program, acknowledged the concern, noting that it is helpful to have guidance but developing guidance documents can be time consuming and is most informed by experience. She said that IRIS staff are trying to balance efforts to move the state of the science forward while making progress on IRIS assessments. Additionally, this is predominantly a chemical-specific issue and it is unlikely that this type of analysis would be warranted for most other chemical assessments.

The large amount of data for BaP allowed IRIS technical staff to craft the first-time DSF, Jones said. "This is the first one that really allowed us to try it," Jones said of the DSF. "It was something we decided to try after discussing with Superfund and other parts of the agency that have been thinking about dermal exposures. We've worked really closely with other parts of the agency. This is a complex issues that is difficult to solve, and there is no scientific consensus on how to do it."

The peer reviewers also raised other challenges for EPA with the remaining toxicity values. EPA's other risk calculations include the inhalation unit risk factor (IUR); the oral slope factor (OSF); the non-cancer reference dose (RfD), or the maximum amount EPA estimates can be ingested daily over a lifetime without anticipating an associated non-cancer health effect; and the reference concentration (RfC). The RfC is analogous to the RfD by inhalation exposure. EPA proposes an IUR of 0.6 per milligram per cubic meter of air; an OSF of 1 per milligram per kilogram body weight per day; an RfD of 3×10^{-4} milligrams per kilogram bodyweight per day and an RfC of 2×10^{-6} milligrams per cubic meter.

The peer reviewers seemed to largely approve of EPA's literature search and the results of its evidence analysis, though they urged EPA to provide greater information to the public on why studies were excluded from the analysis and also to broaden a search for unknown health hazards.

In addition, some of the studies that EPA chose as the basis for chemical toxicity assessments, or the modeling and other approaches used drew concerns from CAAC members. For example, the study EPA used to calculate its IUR, is a study of hamsters exposed to BaP through inhalation means. But the study's weaknesses have been greatly questioned by various stakeholders.

Anne LeHuray, with the Pavement Coatings Technology Council, for instance, asked whether low quality studies were used to calculate the IUR in the IRIS assessment because it's the only study available. LeHuray added that the hamster study was not used in 2001 when EPA created a provisionally peer reviewed toxicity value for EPA's Superfund program.

Advisor Mike Foster, an independent consultant, agreed that there are concerns with the hamster study, but added that there are also some positive attributes, such as the author group replicating the study a few years after the original publication.

Bartell and Leslie Stayner, a peer reviewer and epidemiology professor at the University of Illinois, proposed the idea of using human exposure studies to bolster the IUR, although Bartell noted that such work may prove a challenge for EPA should the analysis not support EPA's.

Similarly, EPA's non-cancer inhalation toxicity estimate also raised some concerns, again in large part due to the study that EPA calculated the risk estimate from. "What surprises me is that they come up with a confidence (level) of low to medium. The confidence is low to non-existent," said Richard Schlesinger, an advisor and associate dean of Pace University's arts and sciences college. "My position is the RfC doesn't have scientific validity. . . . I think they should've decided that they couldn't agree on a reliable RfC for this one study."

"In the current form, the current overall RfC is not supported," concluded Barry McIntyre, a toxicologist with the National Institute of Environmental Health Sciences. "We have serious concerns that the extent of the database is too weak to support an RfC even with low confidence." He suggested that EPA look at two other studies and use the group of studies as the basis for the RfC, rather than relying on one study alone to strengthen the calculation. -- *Maria Hegstad*

Naseera H. Bland

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Ex. 6 Personal Privacy (PP)